REMARKS

The last Office Action of October 23, 2007 has been carefully considered. Reconsideration of the instant application in view of the foregoing amendments and the following remarks is respectfully requested.

Claims 20-39 are pending in the application. Claim 20 has been amended. Claim 39 has been canceled in favor of new claim 40, which now recites more clearly the subject matter previously in claim 39. Claims 41-44 have been added. The fee of $100.00 for submitting four claims in excess of twenty is enclosed. Amendments to the specification have been made to correct an obvious typographic error and to include the term "pulse saving means" which is equivalent to the used term "pulse conservation means" as translation of the German term "Impulseinsparmittel".

The Examiner has objected to the inventor declaration as being defective. Applicant submits herewith a new declaration, reflecting the correct statement with respect to 37 C.F.R. §1.56. The Examiner is directed, however, to the Notice in the Official Gazette of February 12, 2008, vol. 1327, (1327 OG 61), which sets forth that an oath or declaration will be accepted until June 1, 2008, even though it may fail to properly acknowledge a duty to disclose information material to patentability as defined in 37 C.F.R. 1.56.

It is further noted that claim 20 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 20 to provide antecedent basis for all claimed elements. With respect to "memory module" and "memory unit", the Examiner is advised that two separate elements are involved here. Reference is made, e.g. to paragraph **[0043]**, describing the arrangement of a "memory unit 14" and to paragraph **[0047]**, describing the arrangement of a "memory module 21", referred to as an "additional" element for storing the temporal course of the number of applied stimulation pulses. More specifically, the memory module is provided for storing

the temporal course of the number of supplied stimulation pulses, as set forth in paragraph of the instant specification for example, whereas the memory unit is provided to store the number of stimulation pulses transmitted within a definable time interval, as set forth in paragraph **[0011]** of the instant specification. Thus, two distinct components are involved here, when referring to the memory module and the memory unit.

Claims 20-27, 29, 30, 39 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 5,271,396 to Franberg et al. ("Franberg").

Claims 28, 31-32, 36-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Franberg et al. in view of U.S. Pat. No. 4,232,670 to Schulman.

Claims 33-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Franberg et al.

It is noted for the record that the Franberg reference was cited in the international search report and categorized as "X". Still, the International Bureau has determined that the presented claims having novelty and inventiveness. It is believed that claims 20-39 are clearly distinguishable over this reference for reasons which will be hereinafter set forth.

The Examiner asserts that with respect to claim 20, Franberg discloses substantially the invention as claimed, but acknowledged that Franberg fails to disclose the presence of a memory unit, memory module, and the determination of a mean stimulation frequency within the defined time interval. In order to bridge the absence of these claim limitations, the Examiner takes Official Notice and notes that these claim limitations are well known and thus obvious. Applicant respectfully disagrees.

Claim 20 recites a device for stimulating a muscle contraction of a muscular-driven heart assist system which operates in parallel or in series with a diseased heart. A pulse generator unit generates and supplies electric stimulation pulses to a muscle of the muscular-driven heart assist system. Conversely, Franberg discloses a pacemaker which delivers stimulating pulses to the heart itself. This difference between a muscular-driven heart assist system and a

conventional pacemaker is significant for the present invention. One of the objectives of the present invention is to generate and maintain type-IIa muscle fibers and to prevent their conversion to type-I muscle fibers when employing the muscular-driven heart assist system. Type-IIa muscle fibers tend to convert to type-I muscle fibers when the number of muscle stimulation pulses averaged over a relatively long time interval of, for example, several hours (mean stimulation frequency) exceeds a limit value, such as 1 pulse per second which equals about 87,000 pulses per day.

To this end, the claimed device includes a monitoring unit which receives data from the implanted heart assist system, thereby allowing the wearer and/or clinician to monitor the mean stimulation frequency and to make certain adjustments to his/her activities by, for example, resting to lower the heart rate. The presence of a monitoring unit therefore permits an effective supervision of the heart assist system and to inform the wearer about the actual state. Such a feedback is not disclosed in Franberg, which merely provides programming of the pacemaker with a desired heart rate.

As noted above, claim 20 sets forth the presence of a "memory module" in addition to the "memory unit". This combination is not disclosed in Franberg.

Because the present invention is directed to a muscular-driven heart assist system which operates in parallel or in series with a diseased heart and not to a pacemaker which directly stimulates the diseased heart, the mean stimulation frequency, which defined as the number of stimulation pulses of the variable stimulation bursts supplied during the defined time interval (which can be at least 30 minutes, but can also extend over 24 hours), is different from Franberg's stimulation rate which is varied by response amplifier 10 in response to an activity signal. (col. 4, lines 3-5). To prevent damage to type-IIa muscle fibers, the calculated mean stimulation frequency may not exceed a certain limit value. In other words, type-IIa muscle fibers can be maintained and their their conversion to type-I muscle fibers can be prevented by observing a mean stimulation frequency over a time period of, e.g., 24 hours. Franberg only records the stimulation rate

over a predetermined real-time period, i.e., a week to control the response amplification of the response amplifier 10 which transforms the activity signal into a stimulation rate signal. There is no teaching or suggestion in Franberg to include pulse conservation means for reducing the mean stimulation frequency depending on the limit values preset in the evaluation unit, wherein the pulse conservation means comprise a computing unit for computing a stimulation pattern according to an equation which determines the stimulation pattern as a function of the mean stimulation frequency and varies the number of stimulation pulses during a stimulation burst to generate and maintain type-IIa muscle fibers and to prevent their conversion to type-I muscle fibers, as now more clearly recited in amended claim 20.

In order to be clear on this point, claim 20 has been amended to emphasize that a muscular-driven heart assist system is involved here, as opposed to a pacemaker, and to include the effect on type-IIa muscle fibers. This distinction is significant. A pacemaker is a device by which the heart is stimulated by single pulses. Conversely, the present invention is directed to a muscular-driven heart assist system which stimulates a muscle, which operates parallel or serially to the diseased heart, with stimulation bursts to conserve type-IIa muscle fibers, as noted above, and thus to prevent muscle damage. The device according to the invention is used to but not as a pacemaker to stimulate the heart.

For the reasons set forth above, it is applicant's contention that Franberg neither teaches nor suggests the features of the present invention, as recited in claim 20.

Applicant asserts that claim 20 has not been narrowed to trigger prosecution history estoppel.

New claim 40, which includes only subject matter previously presented in claim 39, except for the positive recitation of "generating and maintaining type-IIa muscle fibers and prevent their conversion to type-I muscle fibers" in a muscular-driven heart assist system, recites the step of: "if the mean stimulation frequency exceeds the upper limit value, decreasing the number of the stimulation pulses in

the stimulation bursts so as to reduce the mean stimulation frequency below the limit value and to generate and maintain the type-IIa muscle fibers". As discussed *supra*, type-IIa muscle fibers tend to convert to type-I muscle fibers when the number of muscle stimulation pulses averaged over a relatively long time interval of, for example, several hours (mean stimulation frequency) exceeds a limit value, such as 1 pulse per second which equals about 87,000 pulses per day. Conversely, Franberg is concerned about the stimulation rate supplied to a diseased heart during physical activity, for example, by not changing the stimulation rate even if the activity signal exceeded an upper threshold value (col. 4, lines 7-9). Setting of an upper threshold value is based on the selection of an optimum average rate (col. 6, lines 14-16), whereas the present invention is directed to limiting the number of stimulation pulses applied over a relatively long time interval for generating and maintaining the type-IIa muscle fibers. Accordingly, Franberg fails to teach or suggest the method of the present invention, as recited in claim 40.

US Patent No. 4,232,670 to Schulman also fails to disclose the particular manner in which stimulation pulses are applied to a muscle-driven heart assist system recited in claims 20 and 40, so that Franberg and Schulman, taken either alone or in combination, neither anticipate nor make obvious the features recited in claims 20-38 and 40-44.

In view of the above presented remarks and amendments, it is respectfully submitted that all claims on file should be considered patentably differentiated over the art and should be allowed.

Reconsideration and allowance of the present application are respectfully requested.

Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawing, then it is respectfully requested that such changes be made by Examiner's Amendment, if the Examiner feels this would facilitate passage of the case to issuance. If the Examiner feels

that it might be helpful in advancing this case by calling the undersigned, applicant would greatly appreciate such a telephone interview.

Respectfully submitted,

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